SPINEWAVE

K053336
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510(k) Summary
StaXx™ FX System

I. Submitter Information

Spine Wave, Inc.
Two Enterprise Drive
Suite 302
Shelton, CT 06484
Telephone: 203-944-9494
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Contact: Ronald K. Smith
Date Prepared: April 28, 2006

II. Device Information

Trade name:	StaXx™ FX System
Common name:	Internal Fracture Reduction System
Classification:	Class II per 21 CFR 888.4540; Class II per 888.3027
Classification Name:	Orthopedic manual surgical instrument; Polymethylmethacrylate (PMMA) bone cement
Product Code:	LXH; NDN

III. Device Information

The StaXx™ FX System is a vertebral fracture reduction device composed of stackable wafers fabricated from preformed PMMA. The System includes a base wafer fabricated from PEEK-OPTIMA with 6% Barium Sulfate. The wafers are designed to be inserted incrementally into the vertebral body to form a column that provides the desired fracture reduction. Twenty-four wafers are provided per package. The wafers are provided in one width (8mm) with three lengths (20mm, 25mm, 30mm)

IV. Intended Use

The StaXx™ FX System is indicated for use in the reduction of spinal fractures. It is intended to be used in combination with Stryker Spineplex™ Radiopaque Bone Cement.

V. Substantial equivalence[1]

The StaXx™ FX System was demonstrated to be substantially equivalent to the following devices:

Predicate Device	Manufacturer	510(k) No.
KyphX® Xpander Inflatable Bone Tamps	Kyphon, Inc.	K041454
SKy Bone Expander System	Disc-O-Tech, Ltd.	K040612
KyphX® HV-R™ Bone Cement	Kyphon, Inc.	K041584
Stryker Spineplex™ Radiopaque Bone Cement	Stryker Corporation	K032945
The Wafer System	Spine Wave, Inc.	K033303

In addition, mechanical testing demonstrated that the StaXx™ FX System meets the performance requirements for its intended use. Any differences between the StaXx™ FX and the predicate devices do no affect the safety or effectiveness of this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 3 2006

Spine Wave, Inc.
c/o Mr. Ronald K. Smith
Director, Quality Systems and Regulatory Affairs
Two Enterprise Drive
Shelton, CT 06484

Re: K053336
Trade/Device Name: StaXx™ FX System
Regulation Number: 21 CFR 888.3027, 21 CFR 888.4540
Regulation Name: PMMA bone cement; orthopedic manual surgical instrument
Regulatory Class: Class II
Product Code: NDN, HXG
Dated: April 28, 2006
Received: May 1, 2006

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Packard

for

Mark N. Melkerson
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

A. Indications for Use

510(k) Number (if known): K053336

Device Name: StaXx™ FX System

Indications for Use:

The StaXx™ FX System is indicated for use in the reduction of spinal fractures. It is intended to be used in combination with Stryker Spineplex™ Radiopaque Bone Cement.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bucchi MD

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K053336